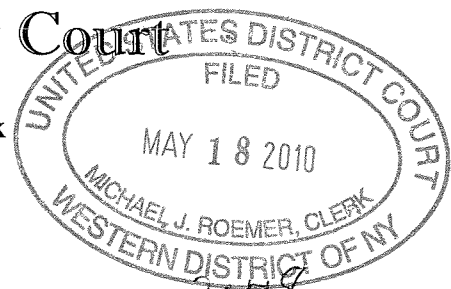


United States District Court

for the
Western District of New York



United States of America

v.

ANTHONY GALEA

Case No. 10 -M - 2078

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief:

In or about September, 2009, in the county of Erie in the Western District of New York and elsewhere, the above-named defendant:

- a) did knowingly import and bring into the United States merchandise contrary to law, in violation of Title 18, United States Code, Section 545 and Section 2;
- b) did knowingly and willfully, in a matter within the jurisdiction of the United States Department of Homeland Security, an agency within the executive branch of the Government of the United States, make materially false statements, in violation of Title 18, United States Code, Section 1001(a)(2) and Section 2;
- c) did knowingly and with intent to defraud introduce and deliver into interstate commerce a new drug, actovegin, for which there had been no approval of an application filed pursuant to subsection (b) or (j) of Title 21 United States Code, Section 355, in violation of Title 21, United States Code, Sections 331(d) and 333(a)(2) and Title 18, United States Code, Section 2.

It is further alleged that:

On or about August 27, 2009, in the county of Erie in the Western District of New York, and elsewhere, the above-named defendant did knowingly possess with intent to distribute human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition where such use had been authorized by the Secretary of Health and Human Services and pursuant to the order of a physician, in violation of Title 21, United States Code, Section 331(e) and Title 18, United States Code, Section 2.

It is further alleged that:

Beginning not later than July 2007 and continuing until in or about September 2009, in the Western District of New York and elsewhere, the above named defendant did knowingly combine, conspire and agree with others:

- a) to knowingly import and bring into the United States merchandise contrary to law, in violation of Title 18, United States Code, Section 545;
- b) to knowingly and willfully make false statements in a matter within the jurisdiction of the United States Department of Homeland Security, an agency within the executive branch of the Government of the United States, in violation of Title 18, United States Code, Section 1001(a)(2);

c) to knowingly and with intent to defraud introduce and deliver into interstate commerce a new drug, actovegin, for which there had been no approval of an application filed pursuant to subsection (b) or (j) of Title 21 United States Code, Section 355, in violation of Title 21, United States Code, Sections 331(d) and 333(a)(2);

d) to knowingly possess with intent to distribute human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition where such use had been authorized by the Secretary of Health and Human Services and pursuant to the order of a physician, in violation of Title 21, United States Code, Section 333(e);

and did commit overt acts to effect the object of the conspiracy, in violation of Title 18, United States Code, Section 371.

It is further alleged that:

Beginning not later than July 2007 and continuing until in or about September 2009, in the Western District of New York and elsewhere, the above named defendant did knowingly combine, conspire and agree with others to defraud the United States and agencies of the United States, including the Department of Homeland Security, and did commit overt acts to effect the object of the conspiracy, in violation of Title 18, United States Code, Section 371.

This criminal complaint is based on these facts:

X Continued on the attached sheet.



Complainant's signature

Justin Burnham, Special Agent, ICE

Printed name and title

Sworn to before me and signed in my presence.

Date: May 18, 2010



Judge's signature

City and State: Buffalo, New York

HUGH B. SCOTT, U.S. Magistrate Judge

Printed name and title

AFFIDAVIT

Justin Burnham, being duly sworn, hereby deposes and states:

1. I am a Special Agent for the United States Department of Homeland Security, Immigration and Customs Enforcement (ICE) and have been so employed since October 2008. As part of my employment with ICE, I successfully completed the Federal Law Enforcement Training Center's Criminal Investigator Training Program, as well as the Immigration and Customs Enforcement Special Agent Training Program. I previously was employed by the United States Immigration and Naturalization Service (INS), the functions of which later were assumed by the Department of Homeland Security. For a period of approximately two years with INS, I was an immigration inspector whose duties included doing primary and secondary inspections at ports of entry. For that position I completed the basic 11-week training course in Brunswick, Georgia.

2. I make this Affidavit in support of a complaint charging Dr. ANTHONY GALEA, who is not a citizen or resident of the United States, with violations of Title 18, United States Code, Section 1001(a)(2) and Section 2 [aiding and abetting the making of false statements in a matter within the jurisdiction of a department of the U.S. government]; Title 18, United States Code, Section 545 and Section 2 [aiding and abetting smuggling]; Title 21, United States Code, Sections 331(d) and 333(a)(2) [introducing an unapproved new

drug into interstate commerce with intent to defraud]; Title 21, United States Code, Section 333(e)(1) and Section 2 [aiding and abetting the unlawful distribution of human growth hormone]; conspiracy to violate the aforementioned statutes, in violation of Title 18, United States Code, Section 371; and conspiracy to defraud the United States, in violation of Title 18, United States Code, Section 371. This Affidavit is made for the limited purpose of establishing probable cause for the above stated offenses, and I therefore do not include within this Affidavit each and every fact pertaining to the investigation.

3. As a result of my training and experience as an agent with ICE, and also my experience as an inspector with INS, I know that determining the true purpose of a person's entry into the United States is an essential part of the inspection procedure at Ports Of Entry. One of the functions of the Department of Homeland Security is to ensure that persons who work in the United States do not do so illegally. The inspection process is intended among other things to prevent persons who seek to enter the country from entering the United States for the purpose of working without authorization. Accordingly, it is a standard procedure for officers performing inspections of non-U.S. citizens and non-U.S. residents to inquire into a person's purpose for coming to the United States. If such a person seeks to enter the United States

in order to work, and if that person does not have authorization to do so, he or she is inadmissible to the United States.

4. I am advised by personnel from the Department of Homeland Security that queries of the pertinent federal data bases have shown no indication that either Dr. Anthony GALEA or any person or entity on his behalf has applied for authorization for Dr. GALEA to work in the United States in any capacity. Despite the absence of such authorization, and, as stated below, despite not being licensed to practice medicine here, Dr. GALEA entered the United States from Canada numerous times from 2007 to September 2009 and worked here as a doctor providing medical services to numerous professional athletes, billed them for services and expenses, and sold medications to them. His billings to three of them whose invoices are discussed herein amounted to approximately \$200,000.

5. I am familiar with the facts of this investigation as a result of my own work and the investigation of agents from the Federal Bureau of Investigation, the Food and Drug Administration, and other agents from ICE. I have also received information from a cooperating witness (CW) who has personal knowledge of many of the facts set forth below, and numerous other persons who have personal knowledge of the facts they have provided to me and to other investigators, all of whom I believe to be credible.

DETAILS OF THE INVESTIGATION

6. As noted above, many of the facts set forth in this Affidavit are based upon information received from the CW. The CW was stopped at the Peace Bridge Port of Entry on a date known to the government in September 2009. As set forth below, during the inspection of CW at the border CW made statements regarding CW's purpose for entering the United States which CW later acknowledged were untrue. Thereafter CW told investigators that CW's true purpose for entering the United States was to travel to the Washington, D.C., area to meet with Dr. GALEA to assist Dr. Galea in performing a medical procedure on a professional football player there. The CW subsequently has told Agents from ICE, FBI, and FDA that since 2007, CW and Dr. GALEA had made numerous trips to the United States for which Dr. GALEA's purpose was to perform medical procedures on professional athletes. The undersigned and other agents from ICE, FBI, and FDA have interviewed several of the athletes the CW identified as patients who received treatments from Dr. GALEA in the United States. These athletes confirmed that they received medical treatments in the United States from Dr. GALEA on a regular basis.

7. The undersigned has examined border crossing records that confirm numerous entries into the United States by Dr. GALEA and CW on days when Dr. GALEA performed medical treatments on professional athletes in the United States. These patients include but are not limited to professional athletes from Major League Baseball, the National Football League (NFL) and the Professional Golfers' Association. Dr. GALEA's billings to three athletes during a period from 2007 to September 2009 is discussed specifically below in paragraphs 26-34 of this Affidavit. Several other professional athletes in addition to those discussed specifically herein were treated by Dr. GALEA in the United States and were billed for services he performed for them here.

8. On a date known to the government in September 2009, a vehicle leased by Galea Investments Incorporated entered an inspection lane at the Peace Bridge Port of Entry in Buffalo, New York. The sole occupant was the CW.

9. The CW told the primary Customs and Border Protection (CBP) Officer that CW was a Canadian citizen. CW was referred to secondary inspection. The CW told the CBP Officer at secondary that CW was traveling to Washington D.C. for a medical conference. CW also said CW had items to display at that medical conference. The secondary Officer saw medical supplies, including syringes,

needles, a centrifuge, and vials and bottles containing liquid substances. Some of those items are identified in paragraph 20 of this Affidavit. The medical supplies included nutropin (HGH) and actovegin, a substance not approved for use in the United States. The CBP Officer referred CW to other CBP Officers for further inspection.

10. The CW told CBP officers that CW was driving to the Buffalo airport and intended to take a flight to Washington D.C. to meet Dr. Anthony GALEA, a Sports Medicine Physician from Ontario, Canada, to attend a medical conference in Washington.

11. The undersigned and other criminal investigators later interviewed the CW at the Peace Bridge. CW repeated many of the statements CW had made during primary and secondary inspection. These included but were not limited to CW's purpose for entering the United States.

12. The CW asked for an opportunity to give agents a truthful account of CW's purpose for entering the United States. The CW then and on subsequent occasions told investigators that the purpose for which CW and Dr. GALEA had come to the United States on that day and on numerous other occasions before then was for Dr. GALEA to provide medical treatments to professional athletes in the

United States. The CW also gave consent for agents to seize and to search the entire contents of a laptop computer, a "Blackberry" cell phone, a GPS device, and a portable ultrasound machine and external hard drive that CW possessed when CW entered the United States.

13. The CW said Dr. GALEA had been providing medical treatments to various professional athletes while inside the United States since 2007. The CW explained that Dr. GALEA treats athletes in the United States during the seasons in which their sports are played. The CW said GALEA is not a licensed doctor in the United States and that Dr. GALEA understood that treating these patients inside the United States was not lawful. The CW said Dr. GALEA travels to various U.S. cities and meets with athletes in hotel rooms and in their residences to provide various forms of treatment. CW said CW arranged the appointments for the treatments. The CW said Dr. GALEA's medical practice is called the Institute of Sports Medicine (ISM) and is located in Etobicoke, Ontario, Canada. The CW said Dr. GALEA would bill the athletes under a company he created called GALEA INVESTMENTS INC.

14. The CW told agents that CW and Dr. GALEA had spoken about what the CW should say or do if CW were interviewed by U.S. border officers about the purpose of CW's trips to the United States. Dr.

GALEA told the CW to tell U.S. Customs officials that CW and Dr. GALEA were coming to the United States only to attend lectures, even though the true purpose for coming to the United States was for Dr. GALEA to provide medical treatment to athletes here.

15. The CW said that in exchange for providing treatments to the athletes and for traveling to the United States for these visits, the athletes paid Dr. GALEA's fees plus travel expenses for Dr. GALEA and for CW when CW made the trips. The CW said invoices were generated in order to bill the patients for medical and travel expenses.

16. The CW said one of the drugs - *actovegin* - that CW brought to the United States on the day in September 2009 referred to above could not be purchased lawfully in the United States or Canada. The CW said that, at Dr. GALEA's direction, a supply of *actovegin* was acquired by CW in Germany in 2007.

17. The CW said Dr. GALEA sometimes left medical supplies with the athletes he was treating in the U. S. These included but were not limited to ginseng, ATP (adenosine triphosphate), and *actovegin*.

18. The CW advised that sometime during evening of the day before the aforementioned date last September, a professional athlete from the Washington, D.C. area called CW in order to meet at a hotel in that area the next day for a treatment session with Dr. GALEA. CW said this athlete rented two hotel rooms for that purpose.

19. The CW said CW packed a medical kit, which included nutropin and actovegin the next morning, in accordance with a checklist CW and Dr. GALEA had made for GALEA's use in the United States.

20. The medical supplies in the CW's possession included but were not limited to: 111 syringes; one centrifuge machine; one GE Ultrasound machine; and a bag with twenty vials and seventy-six ampules of assorted substances and medications, some of which are listed below:

250 ml Actovegin 2000 Proinfusione	1 bottle
1000 mc/ml Vitamin B12	1 bottle
10 mg/2 ml Nutropin	1 bottle
50 ml Procaine HCL 2%	1 bottle
50 ml Marcaine .50% 250mg/50ml	1 bottle
Ginseng Injeel	10 ampules

Adenosin Triphosphate (ATP) 6 ampules
Aktobe**H 17 ampules
5mt-M***pohat 2 ampules
1mt-Hatp**a*eho3*htp**oc*at 5 ampules
[One of these ampules was already broken open at the time of seizure.]

The asterisks [*] denote characters that are not in the English alphabet.

21. Tests were performed by the FDA on some of the substances. The tests confirmed that the contents of a bottle labeled as nutropin was in fact nutropin. Nutropin is human growth hormone (HGH) produced by recombinant DNA technology and is approved for use in adult humans in the United States for a limited number of specified conditions. The conditions for which use of HGH is approved in adults are growth hormone deficiency, AIDS wasting and cachexia, as well as short bowel syndrome. I am advised by FDA that growth hormone deficiency in an adult usually is a continuation of a condition the person had as a child. Otherwise, the condition in adults results from impairment of the pituitary gland caused by a tumor (compression caused by a tumor may inhibit growth hormone production), or damage to the pituitary gland caused by surgery.

22. The tests performed by the FDA on the substance labeled actovegin indicated multiple peptides from bovine fibrinogen, which is consistent with product literature describing actovegin as a deproteinized hemoderivative of calf's blood. I have learned from personnel at FDA that actovegin is not approved for use in humans in the United States.

23. The CW said CW, and not Dr. GALEA, was bringing the medical supplies into the United States because Dr. GALEA had been inspected by United States border officers in Toronto, Ontario, Canada in approximately February of 2009 and was told he could not bring medical supplies into the United States. Computer queries into a U.S. government data base indicate that in February of 2009, Dr. GALEA told inspectors that he was a sports doctor giving a medical lecture in Florida and had medical equipment for the lecture he was giving in Florida.

24. The CW said Dr. GALEA told CW he had been flagged at the border and would not himself be able to bring these items into the United States. The CW said Dr. GALEA then asked CW if CW would be willing to bring the medical supplies across the border for him in the future. CW agreed to do this for Dr. GALEA. The CW said CW subsequently made numerous border crossings into the United States from Canada for Dr. GALEA and that on these trips CW had the same

medical supplies that were found with CW when CW was stopped at the Peace Bridge in September 2009. CW advised that CW did not receive additional compensation for doing this.

25. The medical procedures described by the CW that Dr. GALEA performed in the United States included but were not limited to a plasma rich platelet (PRP) injection, injections of drug mixtures or "cocktails" into athletes' knees; IV drips; and ultrasounds and injections of drug mixtures into the sites of muscle tears. The PRP procedure involved withdrawing blood from a patient, spinning it in a centrifuge, and re-injecting the plasma back into the patient's body at the site of an injury. The CW said this procedure was designed to speed the healing process. The CW said injections into the sites of muscle tears contained actovegin, as did the IV drips. The CW also said Dr. GALEA would at times inject a cocktail containing HGH into an athlete. The CW said HGH injections were designed to help regenerate cartilage growth.

26. Among the professional athletes interviewed during this investigation are three present and former NFL football players who are referred to below as Witness No. 1, Witness No. 2, and Witness No. 3.

27. Agents have reviewed more than fifty invoices regarding Witness No. 1. The CW provided these invoices to the Agents, and CW specifically identified Witness No. 1 as a patient Dr. GALEA saw numerous times in the United States while the CW was present. Witness No. 1 advised Agents that Dr. GALEA treated him regularly during a period that included but was not limited to October 2007 through early September 2009. Witness No. 1 said he understood that Dr. GALEA was not licensed to work in the United States. Witness No. 1 told agents that he specifically discussed receiving actovegin from Dr. GALEA and that he received treatments from Dr. GALEA that included actovegin injections in the United States on numerous occasions. Witness No. 1 has seen bottles of actovegin in Dr. GALEA's possession while the doctor was treating him in the United States. Witness No. 1 denies knowingly receiving HGH and states that he carefully avoided using banned substances (meaning substances banned by the NFL).

28. Witness No. 1 told Agents that Dr. GALEA treated him on a weekly basis in the United States during football season. DR. GALEA would visit Witness No. 1 in the home city for which his team played. Visits sometimes were of more than weekly frequency, especially if Witness No. 1 was bothered by an injury. Among the treatments received by Witness No. 1 were IV drips, injections to the knees, and vitamin B-12 shots to the arm. A typical invoice

charge to Witness No. 1 was \$3,500, but the charge would be less if Dr. GALEA was seeing other players/patients on the same visit. Sometimes the invoices contained charges for gas or travel. They contained little detail regarding the treatments given. A typical description of services would be "Consultation," or "Consultation/IV/Injections." Witness No. 1 stated that he always received some kind of treatment when Dr. GALEA visited him.

29. Witness No. 1 stated that Dr. GALEA mentioned that he could not bring the medications into the country. It was Witness No. 1's understanding that CW brought them into the country because Dr. GALEA could not do that lawfully. Witness No. 1 advised agents that not long after CW was detained in September 2009, Witness No. 1 spoke to Dr. GALEA by phone and Dr. GALEA told Witness No. 1 that he could not treat Witness No. 1 anymore but that at some point he might be able to treat patients lawfully in the United States.

30. I have queried and examined records showing entries into the United States by Dr. GALEA. Along with other Agents, I have compared the dates of invoices issued to Witness No. 1 with dates of some of Dr. GALEA's entries into the United States. Dr. GALEA made approximately thirty entries into the United States at the Peace Bridge Port of Entry in Buffalo, New York on days when he treated Witness No. 1. As noted previously, most treatments took

place in the home city of the team for which Witness No. 1 played and not in Buffalo.

31. Witness No. 2 is a retired NFL football player who also was a patient of Dr. GALEA. The playing career of Witness No. 2 had ended before he became a patient of Dr. GALEA. Witness No. 2 stated that he asked Dr. GALEA about HGH in connection with quality of life issues, and that Dr. GALEA said HGH would benefit him. Witness No. 2 played in the NFL several years and is well above average size in height and weight in comparison with the general population. Witness No. 2 does not recall being diagnosed with any of the three conditions mentioned below (see paragraph 36) for which the use of HGH is approved in the United States. Dr. GALEA did, however, ask that Witness No. 2 have blood tests done.

32. Witness No. 2 recalls seeing Dr. GALEA in mid-August 2009. I have reviewed an invoice to Witness No. 2 dated August 18, 2009. CW's records indicate a treatment of Witness No. 2 by Dr. GALEA in the United States on August 13, 2009. The CW advised that invoices were not always issued on the same day treatments were administered. Records of entries into the United States confirm that the CW entered the United States at the Peace Bridge on August 13, 2009.

33. Witness No. 2 advised that on or about August 27, 2009, CW delivered two "kits" of HGH to his residence in the United States. The kits were for Witness No. 2 and another person (not a professional athlete). The CW confirms that CW brought these HGH kits from Canada to the United States at Dr. GALEA's direction and that on this occasion CW entered the United States at the Peace Bridge in Buffalo, New York. From there CW traveled to the residence of Witness No. 2, which is in another state, and delivered the HGH kits. Records of entries into the United States confirm that the CW entered the United States at the Peace Bridge on August 26 and August 27 of 2009. Witness No. 2 states that the HGH kits were used by himself and the other intended recipient until they ran out. He had been instructed by Dr. GALEA on how to inject himself with the HGH. I have seen the invoice dated August 27, 2009 issued to Witness No. 2. The description for the service on this invoice is simply "2 kits." The substance or substances within the kits is not specified. Each "kit" is priced at \$1,200 for a total of \$2,400.

34. Witness No. 3 is a current NFL football player. The CW identified Witness No. 3 as a patient of Dr. GALEA. Witness No. 3 confirms that he was a patient of Dr. GALEA and received numerous treatments from him in the United States. Witness No. 3 denies that he knowingly received HGH and states that he carefully avoided using

banned substances. He understood that HGH was banned by the NFL. Invoices to Witness No. 3 from Dr. GALEA for the period of July 2007 to October 2009 amount to approximately \$50,000.

FDA Statutes

35. Title 21, United States Code, Section 331(d) provides in relevant part:

The following acts and the causing thereof are prohibited:

...

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.

Title 21, United States Code, Section 355 provides in relevant part:

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application ... is effective with respect to such drug.

As noted above at paragraph 22 of this Affidavit, I am advised by FDA personnel that there has been no approval for the use of actovegin in the United States.

36. Title 21, United States Code, 333(e) provides as follows:


(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2) [pertaining to offenses involving persons under 18 years of age], whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

As noted above at paragraph 21 of this Affidavit, HGH is approved for use in adults in the United States only for growth hormone deficiency, AIDS wasting and cachexia, as well as short bowel syndrome.

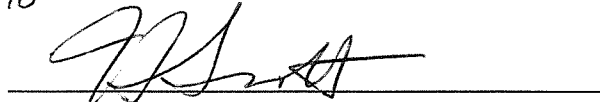
37. Based upon the facts stated above, it is respectfully submitted that there is probable cause that Dr. ANTHONY GALEA has committed violations of Title 18, United States Code, Section 1001(a)(2) and Section 2 [aiding and abetting the making of false statements in a matter within the jurisdiction of a department of the U.S. government]; Title 18, United States Code, Section 545 and Section 2 [aiding and abetting smuggling]; Title 21, United States Code, Sections 331(d) and 333(a)(2) [introducing an unapproved new

drug, actovegin, into interstate commerce with intent to defraud]; Title 21, United States Code, Section 333(e)(1) and Section 2 [aiding and abetting the unlawful distribution of human growth hormone]; conspiracy to violate the aforementioned statutes, in violation of Title 18, United States Code, Section 371; and conspiracy to defraud the United States, in violation of Title 18, United States Code, Section 371.


JUSTIN BURNHAM
Special Agent, ICE

Sworn to before me the

18th day of May, 2010



HONORABLE HUGH B. SCOTT

UNITED STATES MAGISTRATE JUDGE